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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,825	01/11/2002	Yasunori Takada	56769 (71526)	2372

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EXAMINER	
WEBMAN, EDWARD J	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/030,825	TAKADA ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5 and 7-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5 and 7-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 7, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al.

Patel et al teach a topical gel composition containing medicaments (abstract). 0.005% to about 10% medicament is specified (column 4 lines 48-49). Diclofenac is disclosed (column 4 line 67). Ammonium chloride at 0.01-5% is specified (column 8 lines 19-38). Sustained efficacy is disclosed (column 3 line 13).

It would have been obvious to one of ordinary skill in the art to make a composition comprising a gel including diclofenac and ammonium chloride to achieve the beneficial effect of sustained efficacy in view of Patel et al. As to the claimed molar ratio, the molar range of diclofenac is 0.0002-0.9 moles per liter and that of ammonium chloride is 0.002-0.3 moles /per liter. That is, the molar ranges overlap, including 1:1 ratio. An optimum suitable range is obtained by routine experimentation.

At the outset, applicants argue intended use. However, intended uses in composition claims are not considered patentable limitations during prosecution before the USPTO. Applicant also argues that Patel et al does not teach sodium diclofenac. However, sodium diclofenac is the diclofenac of commerce. Applicants also argue that Patel does not disclose ammonium chloride, citing column 8 lines 12-20 and then stating that no other portion of column k discloses the agent. However, column 8 lines

30-33 stating "Equivalent amounts of of one or more salts made up of cations such as potassium, ammonium and the like and anions such as chloride . . .", clearly indicates that ammonium chloride is contemplated.

Claims 1, 4, 5, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledger et al in view and Inagi et al.

Ledger et al teaches a matrix for transdermal administration of a drug and an antigen processing-inhibiting agent is disclosed (abstract). 0.2%-20% weak base antigen processing-inhibiting agent of the drug is disclosed (column 9 lines 64-68). Ammonium chloride is specified (column 5 line 34). Analgesic agents including ketoprofen are disclosed (column 4 lines 45 and 63). An adhesive layer containing the agent and drug is specified (column 7 lines 8-9). Ointments are disclosed (column 6 line 37). Reducing sensitization is specified (column 3 lines 34-37).

It would have been obvious one of ordinary skill to make a matrix comprising an analgesic such as ibuprofen and ammonium chloride to achieve the beneficial effect of reducing sensitization in view of Ledger et al. As to the claimed diclofenac and adhesive base, Inagi et al teach the equivalence of ketoprofen to diclofenac as an analgesic (column 8 lines 1-8) in an acrylic adhesive base material (abstract). Thus, it would have been further obvious to use diclofenac as the analgesic and acrylic as an adhesive in the composition of Ledger et al in view of the fact that the former is known in the art as equivalent to ibuprofen and the latter is known in the art as an adhesive in view of Inagi et al. As to the claimed molar ratio, 0.2-20% ammonium chloride of

diclofenac is equivalent to 0.04-0.4 moles of the ammonium chloride to 0.3 moles of diclofenac. That is, the molar range of ammonium chloride overlaps the molar amount of diclofenac to include a 1:1 ratio. An optimum suitable range is obtained by routine experimentation.

Applicants argue that Ledger et al does not teach ibuprofen. Applicants are correct; however, the examiner had clearly intended to recite ketoprofen, for which the obvious combination works. Applicants again argue an intended use, but such an argument, as noted in the first 103, is not germane for the reason supplied *supra*, as applied to the instant rejection. Applicants argue that the Ledger et al and Inagi et al are directed to different objectives. However, both deliver NSAIDS and both contain adhesives.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).